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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,399	09/27/2000	Masao Washizu	001268	7255

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EXAMINER	
BROWN, JENNINE M	

ART UNIT	PAPER NUMBER
1755	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/670,399	WASHIZU ET AL.
	Examiner	Art Unit
	Jennine M. Brown	1755

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 14-25* is/are pending in the application.

4a) Of the above claim(s) *11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 14-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

The amendment filed 8/19/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "which is formed by electrodes which are not light sensitive". This negative limitation added in the amendment in claims 1, 2, 4, 5, 6, 7, 14, 15, 16 and 17 is not explicitly supported in the specification or claims as originally filed. In Applicant's own arguments they admit that "are not light-sensitive" is not explicitly defined in the specification on page 15 of the Response filed August 19, 2004. This constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims Analysis

For purposes of furthering prosecution and clarifying the record, the examiner is interpreting the terms used in the instant application and claims as having the following meaning:

1. "specific molecule" is interpreted as a "particle".

2. Anything that binds to the particle either temporarily or permanently is interpreted as a "ligand". The term "ligand" according to www.merriamwebster.com is defined "a group, ion or molecule coordinated to a central atom or molecule in a complex".

3. Anything which causes the particle or the ligand or any combination or subcombination to produce a detectible signal will be considered a "label". The term "label" previously used appropriately by the Examiner is in the "transitive verb" case. According to www.merriamwebster.com is defined "**1a:** to affix a label to **b:** to describe or designate with or

as if with a label **2a:** to distinguish (an element or an atom) by using an isotope distinctive in some manner (as in mass or radioactivity) **b:** to distinguish (as a compound or cell) by introducing a traceable constituent (as a dye or labeled atom)".

4. Anything that detects the label to be a "detection method". Anything as defined in this particular instance only, means any method or apparatus used to detect the label not "any series of steps".

The definitions supra are given by the Examiner to clarify for the record the more common terminology already in use in the art and to better define the terminology used in the claims by relating them to the terminology used in the prior art in order to make clear the rejections made below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 15-17, 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Parton, et al. (US 5993631).

Parton, et al. disclose a method of separating a first population of particles from a second population of particles where first population is bound to a ligand and a label which changes the properties of the first population of particles and the second is unbound affecting a separation between the first and second population in a dielectrophoretic field (col. 2, l. 46-58).

The population of particles disclosed are mammalian cells, plant cells, yeast cells, chromosomes undergoing meiosis or mitosis, oocytes, other chromosomes, bacterial cells, viruses, DNA, RNA and proteins (aka "sample derived from a living body" - col. 3, l. 6-12). The ligands disclosed which bind to the particle can be an antibody, antigen, nucleic acid probe, nucleic acid analog, avidin or avidin like substance (col. 3, l. 31-37; Figures 8-12). Labels disclosed can be magnetic, fluorescent markers, chromophores, enzyme molecules or anything that will produce a detectible signal (col. 4, l. 36-60; Figures 9-12). It is disclosed that the separation between the microelectrodes is 30 μm to 80 μm which are 5 to 20 times larger than the size of the particles (col. 6, l. 52-57). At least one detection method is disclosed for detecting the separated particles (col. 7, l. 29-40; col. 8, l. 29-41; Figure 7). The dielectrophoretic force disclosed is based on the movement of the particle and is related to the frequency of the rotating field from 10 to 10^{10} Hz (col. 11, l. 9-13; col. 12, l. 38 – col. 13, l. 23; Figures 14-16). The electrodes disclosed are capable of horizontal and vertical non uniform fields (Figures 1-6).

Claims 1-10, 14-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Seul, et al. (US 638707 B1).

Seul, et al. disclose a method of separating a first population of particles from a second population of particles where first population is bound to a ligand and a label which changes the properties of the first population of particles and the second is unbound affecting a separation between the first and second population in a dielectrophoretic field. (col. 2, l. 34-37; col. 18, l. 65 – col. 22, l. 22) The population of particles disclosed are lipid vessicles, whole chromosomes, cells, DNA and proteins (aka "sample derived from a living body" - col. 2, l. 39-47). Seul, et al. illustrate both separation and detection techniques for multiple species in the schematics of Figures 8, 9a, 10, 22, 23, 26 and 27. Labels disclosed as enzyme molecules or

anything that will produce a detectible signal (col. 26, l. 30 – col. 27, l. 34) and quantitative detection is disclosed (col. 35, l. 1 – col. 38, l. 35). Specific examples of immunophenotyping (col. 39, l. 40-56), multiplexed affinity detection (col. 39, l. 60 – col. 40, l. 5) and cellular based functional assays (col. 40, l. 25-54).

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Becker, et al. (US 6294063).

Becker, et al. teach an equivalence between movement of sample ("packets") by electrophoretic forces and dielectrophoretic forces (Figure 2; col. 3, l. 42-46; col. 7, l. 63 – col. 8, l. 5; col. 8, l. 31-35). Becker, et al. also teach a method of forming a complex substance to separate out a specific molecule from a mixture by applying a dielectrophoretic field then detection to give qualitative measurement of the separated specific molecule where the application deals with separation of proteins, nucleic acids and cells (Figures 1, 9B, 12; col. 2, l. 59-63; col. 3, l. 17-23; col. 4, l. 6-10; co. 5, l. 66 – col. 7, l. 4; col. 14, l. 46 – col. 15, l. 7; col. 28, l. 28 – col. 30, l. 44).

Response to Arguments

Applicant's arguments filed 8/19/2004 have been fully considered but they are not persuasive.

1. New matter introduction by the use of the phrase "which is formed by electrodes which are not light sensitive". This negative language limitation constitutes new matter as there is no explicit support in either the specification or claims as previously presented. Applicant is required to cancel the new matter in the reply to this Office Action.

2. Claims analysis definitions have remained the same. Examiner has added definitions from www.merriamwebster.com supra in evidence of the correct usage of each of

the terms defined in order that the rejections are clear for the record. The claims analysis is not required and was not disclosed to define the claims language as alleged by Applicants but to equate the prior art language with that of Applicant's claim language.

a) Regarding the term "ligand" not being present in the claims, "ligand" would be equated to a "substance capable of changing dielectrophoretic properties of the specific molecule" which is in the claims. See the definitions given previously supra.

b) Regarding Applicant's assumption that the phrase "detection method" means "any series of steps" is incorrect. Examiner regards "detection method" as any method that uses a label, which produces a detectable signal or change in speed, trajectiory, path, or other property that can be measured by any apparatus.

3. Parton, et al. do inherently disclose a non-uniform electric field strength of 500 kV/m or higher and does not relate to the gap between adjacent electrodes or other calculation as alleged by Applicants. Parton cited the following prior art: Price, Burt and Pethig, *Biochemica et Biophysica*, Vol. 964, pp. 221-230 in evidence of standard fabrication methods for the apparatus. The abstract therein states "Results are presented for *Micrococcus lysodeikticu*, *Bacillus subtilis* and *Escheria coli* for the frequency range 20 Hz to 4 MHz and theoretical considerations are presented for the effect of solution conductivity. A value of 0.2 S/m has been derived for the effective conductivity of *M. lysodeikticus*." Since the frequency given is within the frequency range claimed in instant claim 24, the examiner points to this as evidence of its inherent property for field strength. The claims as written do not distinguish the claimed material over the prior art therefore the rejection stands.

4. *Seul, et al.* The newly added limitation was addressed in the new matter rejection supra. As originally presented and as evidenced in Applicant's specification on page

41, the only property required of the electrode is that it be capable of forming a horizontally and vertically non uniform electric field and its structure can be any structure capable of causing dielectrophoretic forces. Although conductive metal materials are cited, the phrase "or the like" is used which may include semiconductor materials. Furthermore the limitation that the electrodes are "not light sensitive" is somewhat inaccurate. All metals and particularly transition metals and metalloids are light sensitive in that they have the ability to be used for photoelectric processes when impinged upon by light of the proper frequency. The claims as written do not distinguish the claimed material over the prior art therefore the rejection stands.

5. Becker, et al. specifically teach a method of forming complex substances to separate out a specific molecule in part through the illustrations given in Figures 1, 11, 12 and 13. When the disclosure states that "a position of one or more obstructions on the reaction surface may be determined. The interacting of one or more packets may include moving, fusing, merging, mixing, reacting, metering, dividing, splitting, sensing, collecting or any combination thereof" which would be different methods which can be used to form complex substances. In column 22, lines 45-52 disclose, "In the middle pane, two packets, starting at different locations upon the reaction surface, are directed, via appropriate electrical signals, to come together at a specified location (near the center of the array) to fuse together, for example, to initiate a reaction. The fused packet may be manipulated just as the original packets were manipulated." See also the example Avidin Actin PSL in column 23. The non uniform electric field is addressed in part in Figure 2 which shows the anode and cathode and two particles in a dielectrophoretic field. The generator may give AC or DC fields and specifically are between 100 Hz and 20 MHz and from 10 to 100 V peak to peak in column 26, line 25-37,

are within the claimed range in claim 24 of the instant application. The claims as written do not distinguish the claimed material over the prior art therefore the rejection stands.

6. Obviousness double patenting rejection. Based on the current amendment to the copending claims of 09/833,566, the provisional obviousness double patenting rejection has been withdrawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennine M. Brown whose telephone number is (571) 272-1364. The examiner can normally be reached on M-F 8:00 AM - 6:00 PM; first Friday off.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on (571) 272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jmb

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